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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

PABBAN DEVELOPMENT, INC.,

Plaintiff,

vs.

KYPHON SÀRL, MEDTRONIC, INC., AND DOES 1-100,

Defendants.

KYPHON SÀRL and MEDTRONIC, INC.,

Counterclaimants,

vs.

PABBAN DEVELOPMENT, INC., BIO-MEDICAL DEVICES, INC., BIO-MEDICAL DEVICES INTERNATIONAL, INC., and HARRY N. HERBERT,

Counterdefendants.

No.: SACV 10-533 CJC (RNBx)

DEFENDANTS KYPHON SÀRL AND MEDTRONIC, INC.'S SECOND AMENDED COUNTERCLAIM AND DEMAND FOR JURY TRIAL

Honorable Cormac J. Carney

Pursuant to the Court's minute order dated August 3, 2011, Defendants Kyphon Sàrl ("Kyphon") and Medtronic, Inc. ("Medtronic") amend their counterclaim as follows:

1. Pabban Development, Inc. ("Pabban") is a California corporation with its principal place of business in Irvine, California.

2. Bio-Medical Devices, Inc. ("BMD") is a California corporation with its principal place of business in Irvine, California.

3. Bio-Medical Devices International, Inc. ("BMDI") is a California corporation with its principal place of business in Irvine, California.

4. Pabban, BMD and BMDI are affiliated companies.

5. Harry N. Herbert ("Herbert") is the Chief Executive Officer of Pabban and is responsible for the day-to-day operations of Pabban, BMD and BMDI.

6. Herbert, directly or indirectly, owns a controlling interest in Pabban, BMD and BMDI.

7. Kyphon is in the business of selling products used in the treatment of spinal fractures. In appropriate circumstances, such fractures may be treated by injecting bone cement into the vertebra in the spine and filling the cavity. The cement reinforces the walls of the vertebra, which prevents compression. The medical device used to inject the cement into the vertebra is known as a "bone filler device."

8. Medtronic is the global leader in medical technology – alleviating pain, restoring health and extending life for millions of people around the world.

9. In late 2007, Kyphon was in the very early stages of developing an improved "bone filler device." However, Kyphon expected that this potential new offering would not be market-ready until at least May 2009 – significantly after it anticipated its competition would offer similar devices for sale. If those competitors beat Kyphon to the market, they would obtain a "first to market" advantage. The "first to market" advantage can be critical in the medical device industry because even a several month head start can significantly damage a competitor's potential market share. Based in part on the fact that its potential new offering would not be "market-ready" until May 2009 and its competitors were farther along in the development process, Kyphon was interested in purchasing a market-ready product to avoid losing critical market share.

10. At the same time, Kyphon was considering whether to develop a new "bone filler device." BMD, BMDI and Pabban had developed such a device, which was called the Natrix Bone Cement Delivery System ("Natrix System"). BMD and BMDI owned the tooling for the Natrix System, Pabban owned the assets related to the product, and Syntech International, Inc., manufactured the product. Kyphon became aware of the "Natrix System" and communicated to Pabban and Herbert an interest in learning more about it to determine if Kyphon should continue to develop its own product or purchase the market-ready "Natrix System."

11. As a part of Kyphon's initial discussions with Herbert, he represented to Kyphon that the Natrix System had four principal advantages over Kyphon's existing "bone filler device."

- First, the Natrix System reduced radiation exposure for physicians using the device;

- Second, the Natrix System generated pressure of over 1500 psi, which allowed it to deliver much preferred higher viscosity cement than that delivered through other injection systems on the market;

- Third, the Natrix System could be operated with one hand, which was of interest to physicians; and

- Fourth, unlike any other product on the market, a physician using the Natrix System could instantly halt cement flow.

12. In November 2007, Kyphon met with Pabban, BMD, BMDI, and Herbert at BMD and BMDI's facility. At that meeting, Pabban, BMD and BMDI not only demonstrated the Natrix System, but Herbert represented that the product had been used successfully in 30-40 live procedures, and had been through at least eight rounds of marketing trials. Representatives of Kyphon, including Kyphon's CEO, Bob White, told Herbert if Kyphon purchased the Natrix System, it intended to launch the Natrix System at the prestigious and very important North American Spine Society ("NASS") conference in October 2008. Herbert, on behalf of Pabban, BMD and BMDI, repeatedly assured Kyphon that the Natrix System was ready for market.

13. In addition to representing to Kyphon that the Natrix System was ready for market, Pabban, BMD, BMDI, and Herbert represented to Kyphon that:

- If BMD and BMDI did not sell Natrix to Kyphon, BMD and BMDI would start selling the product itself "within 30-45 days."

- BMD and BMDI planned to release Natrix "by end of March [2008]."

- As BMD and BMDI moved forward "with our marketing trials and production processes to our April 2 [2008] market release, we continue to validate the NATRIX market capabilities."

- Natrix is an "Immediately Accretive class one device, production-ready."

14. After these initial meetings, Kyphon conducted an "on-site" due diligence session at BMD and BMDI's facility on May 22-23, 2008. Kyphon conducted a second (and final) on-site due diligence session on June 12, 2008.

15. On August 7, 2008, Kyphon and Pabban entered into an Asset Purchase Agreement ("APA").

16. Prior to closing of the APA, Kyphon requested permission to test the Natrix System in its own facilities. Pabban refused Kyphon's request because of purported concerns with confidentiality. It turns out, however, that Pabban refused to provide Kyphon with access to the Natrix System for testing because such testing may have revealed the product was defective and not market-ready.

17. After the APA closed, Kyphon learned that the Natrix System was unmerchantable and defective at the time Kyphon purchased it from Pabban. The device uses a hydraulic delivery system to push bone cement through the delivery tube. Saline fluid resides in a polyurethane bag inside the handle of the device. In August 2008, after the APA closed, Kyphon received its first shipments of Natrix

devices manufactured by Syntech International, Inc. ("Syntech"). Kyphon thereafter discovered fluid inside the packaging, which suggested the devices were leaking saline. After conducting an investigation, Kyphon determined that two defects caused the leaks. First, the seams or "welds" on the saline bag were weak and subject to splitting. Second, the manner in which the bag was sealed to the device with an O-ring allowed saline to leak between the bag and the O-ring. Kyphon had no way of knowing of the leaks prior to the closing of the APA. In fact, Pabban, BMD, BMDI and Herbert took steps to conceal the leaks from Kyphon.

18. In May 2008 (prior to the August 7 closing of the APA), Pabban provided Kyphon with a copy of Pabban's Design Failure Mode and Effects Analysis ("DFMEA") and Process Failure Mode and Effects Analysis ("PFMEA"). These documents, which are standard in the medical device industry, track problems with a device during development, and document how and when the problems were solved. While the documents note pre-closing leaks associated with the O-ring and saline bag, they represent that both issues were corrected and the matters were "closed" on May 21, 2008 – one day ***before*** Kyphon's first due diligence visit.

19. After the closing, Kyphon misplaced the disk that contained the Design History File that Pabban provided to Kyphon prior to the closing. Kyphon then asked Pabban provide another copy of the DHF, which Pabban did. That second DHF, however, included a "Performance Qualification Protocol" that sets forth test parameters relating to the detection of saline leaks in the Natrix System. That document is dated August 7, 2008 – the date of the closing. The document shows that Pabban was attempting to correct dangerous saline leaks ***on the same day*** that Kyphon paid Pabban in excess of $18 million for a medical device that Pabban represented was market-ready and to be used on patients.

20. The saline leak posed a number of problems, including the inability to properly sterilize the Natrix System. Not surprisingly, a medical device like the Natrix System must be sterilized before it can be used during an operation. The process used to sterilize the Natrix System is known as "gamma radiation sterilization." After sterilization, the product should show a "bioburden count" of less than 2000 "colony forming units" or CFU's.

21. After the APA closed, the Natrix devices delivered to Kyphon were packaged individually in sealed trays. The outside of each package bore the following label:

> Single use only. Do not reuse or resterilize.
> Sterile only if pouch is unopened and undamaged.

In addition, a "Product Information Data Sheet" was inside each sealed package. That document provided, in part, as follows:

> The contents of the inner package (tray) are gamma sterilized. Contents are only sterile if the inner package is not open, damaged, or broken.

22. Kyphon opened the packages and tested whether the devices had been sterilized properly. Kyphon's testing showed unacceptably high bioburden counts, which rendered the device unmerchantable. Simply put, an unsterilized Natrix System could not be sold for use during an operation on a patient's spine.

23. Kyphon raised the bioburden issue with Pabban. On September 23, 2008, Pabban sent an email to Kyphon in which Pabban admitted that the bioburden problems were caused by the undisclosed saline leaks:

> I also spoke with Fred Weber (President of Sterility Assurance Laboratories) yesterday. I spoke to him about our bioburden issue on the delivery gun. He feels strongly that the saline exposure is the cause of the high bioburden counts.

24. On September 17, 2008, Kyphon sent an email to Pabban complaining of the defects. Pabban responded with an email on September 18, 2008, in which Pabban admitted that the devices were "unacceptable" and a "disappointment":

> ... I agree that there has been some quality related issues that are unacceptable, and frankly a disappointment to me.

25. In October 2008, Kyphon retained its own expert, SteriPro Labs, to perform bioburden testing. SteriPro's report showed CFU's that were "too numerous to count," which means that the device is simply not sterilizable. Such a device presents a danger of serious injury or death and, therefore, cannot be sold.

26. Prior to the close of the APA, Kyphon reviewed documentation that showed Pabban was using 27.5 kilogray to sterilize the devices, when 25 kilogray should have been sufficient. Kyphon asked Pabban why Pabban was using 27.5 kilogray. Pabban responded that it did not know why. After the closing, and after the bioburden problems were discovered by Kyphon, it again raised the issue with Pabban. At that time, Pabban reluctantly acknowledged that Pabban did indeed have pre-closing bioburden problems.

27. The defects in the Natrix System made the product dangerous and unmerchantable because they posed a serious and prohibitive risk to patients. Therefore, on October 21, 2008, Kyphon terminated the Supplier Agreement with Syntech. Syntech did not challenge the termination.

28. Kyphon immediately began the process of correcting the defects. That process included significant research and development efforts, followed by compliance testing and validation. However, that process caused sales of the product to be delayed and Kyphon lost the "first to market" advantage that it sought and for which it paid.

29. In September 2009, after an eleven month delay caused by the defects described herein, Kyphon launched the Kyphon Cement Delivery System. Because of the delay, Kyphon lost substantial sales and market share, which reduced the value of the Natrix System by an amount in excess of $40 million.

30. The APA the parties negotiated provides a remedy for Pabban's failure to deliver the product it agreed to deliver. By way of example, as set forth more fully below, Pabban represented and warranted to Kyphon and Medtronic, among other things, that the Natrix System was free from significant defects, suitable for its then current use, of merchantable quality, and suitable for its intended and labeled purpose.

31. In Section 3.9 of the APA, Pabban warranted that:

> Title to and Condition of the Purchased Assets. Seller has full right, title and interest to the tangible Purchased Assets, free and clear of all Liens. The Purchased Assets (other than the Retained Assets or the Business Intellectual Property) include all assets, properties, rights, interests and

claims necessary for the conduct of the Business and all assets, properties, rights, interests and claim owned or controlled by Seller or an Affiliate of Seller that relate to the development, manufacture, commercialization or sale of products related to the Business. **The Purchased Assets (other than the Retained Assets or the Business Intellectual Property) are suitable for the uses for which they are presently used by Seller, in normal operating condition and free from any significant defects, ordinary wear and tear excepted.** The Purchased Assets include at least those assets listed on Schedule 3.1.1 through 3.1.4 (other than the Retained Assets). Except as specifically set forth on Schedule 3.9, all of the Purchased Assets are located at the facilities of Seller.

(emphasis added).

32. In Section 3.16 of the APA, Pabban warranted that:

Manufacturing Processes. Seller has delivered or made available to Kyphon or its Affiliates complete and accurate written documentation of the processes and procedures used or necessary to manufacture the Natrix System as it is currently conducted (the "Manufacturing Documentation"). **To Seller's Knowledge, the Natrix System, as presently designed and configured, and, when manufactured in accordance with the Manufacturing Documentation, will materially conform to the specifications established therefor and to Seller's Knowledge will be (a) of merchantable quality; (b) free from defects in design, material and workmanship; and (c) suitable for their intended and labeled purpose.** The Business Intellectual Property

> includes all the Manufacturing Documentation and all processes, methods, techniques, procedures, trade secrets and know how included therein.

(emphasis added).

33. Section 7.1 of the APA mandates that Pabban indemnify Kyphon for all damages, including attorneys' fees, that result from Pabban's breach of the APA. The APA provides:

> [Pabban shall] indemnify, defend and hold harmless [Kyphon]. . . from and against and in respect of any and all paid or incurred losses, damages, liabilities, assessments, interest and penalties, costs and expenses (including, without limitation, reasonable legal fees and disbursements incurred in connection therewith and in seeking indemnification therefore, and any amount or expenses paid or incurred in connection with any action, suit, proceeding, claim, appeal, demand, assessment or judgment), whether or not involving a third party claim, (collectively "Indemnifiable Losses") directly or indirectly resulting from, arising out of, or imposed upon or incurred by any person to be indemnified hereunder by reason of . . . any breach of any representation or warranty of [Pabban].

34. In addition, the APA grants Kyphon the right to withhold payments to Pabban based on Indemnifiable Losses. In particular, Section 7.3 of the APA provides, in pertinent part, that "Kyphon shall have the right to set-off any claims for Indemnifiable Losses . . . against any payments due and owing to Seller . . . and not yet paid."

35. Pabban, BMD, BMDI, and Herbert were aware of the defects, and hid them from Kyphon.

36. The Natrix System was not suitable for the uses for which it was used by Pabban at the time of the closing.

37. The Natrix System was not in normal operating condition at the time of closing of the APA.

38. The Natrix System was not free from significant defects at the time of the closing of the APA.

39. At the time of the closing of the APA, the Natrix System, as it was then designed and configured, and, when manufactured in accordance with the Manufacturing Documentation, did not materially conform to the specifications established therefore.

40. At the time of the closing of the APA, the Natrix System was not of merchantable quality.

41. At the time of the closing of the APA, the Natrix System was not free from defects in design, material and workmanship.

42. At the time of the closing of the APA, the Natrix System was not suitable for its intended and labeled purpose.

43. Pursuant to its rights under the APA, Kyphon justifiably withheld milestone payments that may have been otherwise due under the APA.

CLAIM I

BREACH OF CONTRACT

(AGAINST PABBAN)

44. The allegations contained in paragraphs 1-43 of this counterclaim are adopted and incorporated herein by reference as if fully set forth herein.

45. Pabban breached the APA.

46. As a result of Pabban's breach, Kyphon has been damaged in an amount exceeding $75,000 exclusive of interest and costs, to be determined at trial.

47. As a result of Pabban's breach, Kyphon is entitled to recover its costs, disbursements, and attorneys' fees incurred in this matter pursuant to Section 7.1 of the APA.

CLAIM II

BREACH OF THE DUTY OF GOOD FAITH AND FAIR DEALING

(AGAINST PABBAN)

48. The allegations contained in paragraphs 1-43 of this counterclaim are adopted and incorporated herein by reference as if fully set forth herein.

49. The APA is governed by Delaware law. Under Delaware law, an obligation of good faith and fair dealing is implied into the APA by law. Therefore, pursuant to the APA, Pabban had an obligation to deal with Kyphon fairly and in good faith.

50. Pabban knew that Kyphon was willing to enter into the APA because Kyphon desired a quick entry into the market and in reliance on Pabban's

representation that the Natrix System was ready for sale in 2008. As a result, Pabban was obligated to inform Kyphon about any problems associated with the Natrix System that would prevent an imminent commercial release, including but not limited to the saline leak and bioburden problems that postponed the commercial release of the product for more than a year. By failing to do so, Pabban breached the covenant of good faith and fair dealing implied in the APA.

51. As a result of Pabban's breach of its duty of good faith and fair dealing, Kyphon has been damaged in an amount exceeding $75,000 exclusive of interest and costs, to be determined at trial.

52. As a result of Pabban's breach, Kyphon is entitled to recover its costs, disbursements, and attorneys' fees incurred in this matter pursuant to Section 7.1 of the APA.

CLAIM III

FRAUD

(AGAINST PABBAN, BMD, BMDI, AND HERBERT)

53. The allegations contained in paragraphs 1-43 of this counterclaim are adopted and incorporated herein by reference as if fully set forth herein.

54. Pabban, BMD, BMDI, and Herbert made representations to Kyphon.

55. Pabban, BMD, BMDI, and Herbert's representations were false. For example, but not by way of limitation:

- At the time of the closing of the APA, the Natrix System was not suitable for the uses for which it was then used by Pabban;

- At the time of the closing of the APA, the Natrix System was not in normal operating condition;

- At the time of the closing of the APA, the Natrix System was not free from significant defects;

- The Natrix System, as designed and configured at the time of closing of the APA, when manufactured in accordance with the Manufacturing Documentation, did not materially conform to the specifications established therefore;

- At the time of the closing of the APA, the Natrix System was not of merchantable quality;

- At the time of the closing of the APA, the Natrix System was not free from defects in design, material, or workmanship;

- At the time of the closing of the APA, the Natrix System was not suitable for its intended and labeled purpose.

56. At the time Pabban, BMD, BMDI, and Herbert made the representations set forth above, they knew those representations were false.

57. Pabban, BMD, BMDI, and Herbert made the representations with the intent to induce Kyphon to purchase the Natrix System.

58. Kyphon relied on Pabban, BMD, BMDI, and Herbert's representations, and Kyphon was justified in relying on Pabban's representations.

59. As a result of Pabban's misrepresentations, Kyphon has been damaged in an amount exceeding $75,000 exclusive of interest and costs, to be determined at trial.

CLAIM IV

DECLARATORY RELIEF

(AGAINST PABBAN)

60. Medtronic adopts and incorporates by reference as if fully set forth herein paragraphs 1-43 of this counterclaim.

61. An actual controversy has arisen and now exists between Medtronic and Pabban concerning their respective rights and obligations under the APA.

62. Medtronic contends that it has no obligations to Pabban whatsoever, including any purported obligation to guaranty any alleged obligation of Kyphon.

63. Pabban disputes this contention and contends that Medtronic is obligated to guaranty the purported obligation of Kyphon to make milestone and royalty payments for sales of the Natrix System.

64. A judicial declaration is necessary and appropriate at this time under the circumstances, in order that Medtronic may ascertain its rights and duties under the APA. Declaratory relief would resolve Pabban's allegation that Kyphon breached the APA by not making certain milestone and royalty payments as set forth in the APA.

WHEREFORE, Kyphon and Medtronic demand judgment against Pabban, BMD, BMDI, and Herbert as follows:

1. Money damages in an amount exceeding $75,000, the exact amount to be determined at trial:

a. Against Pabban for breach of the APA and for fraud; and

b. Against BMD, BMDI and/or Herbert, for fraud;

2. Awarding Kyphon and Medtronic their costs and attorneys' fees incurred herein;

3. A determination that Medtronic has no obligation to Pabban under the APA, including but not limited to any purported obligation to guaranty the payment of milestones and royalties;

4. Punitive damages in an amount to be proven at trial; and

5. For such other and further relief as the Court deems just and equitable.

DEMAND FOR JURY TRIAL

Kyphon Sàrl and Medtronic, Inc. hereby demand a jury trial.

DATED: August 23, 2011.

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